

Patient Safety Learning's response to the Women's Health Strategy: Call for Evidence

This is a submission by [Patient Safety Learning](#) as part of the Women's Health Strategy: Call for Evidence.

Patient Safety Learning is a charity and independent voice for improving patient safety. We harness the knowledge, insights and commitment of health and social care organisations, professionals and patients for system-wide change and the reduction of avoidable harm.

We support safety improvement through policy, influencing and campaigning and the development of 'how to' resources such as [the hub](#), our free award-winning platform to share learning for patient safety.

Patient safety and avoidable harm

In the UK, there are an estimated 11,000 avoidable deaths annually, with patient safety issues costing the NHS over £5bn a year. Globally, WHO estimates that unsafe care is one of the 10 leading causes of death and disability.

To achieve a patient-safe future, we believe that instead of focusing on *responding to harm*, healthcare needs to *design for safety* and move from being *reactive* to become *proactive* in keeping patients safe. As outlined in our report [A Blueprint for Action](#), we identify six evidence-based foundations for safer care: Shared Learning, Leadership, Professionalising patient safety, Patient engagement, Data and insight, and Culture.

Women's health and patient safety

To inform the development of the Women's Health Strategy, this consultation has asked for written submissions of data, research, and reports of relevance to women's health. In this response we have included a recent evidence-based blog we published for International Women's Day concerning the risk to patient safety resulting from sex and gender bias.

The consultation seeks views on 6 core themes that connect different areas of women's health across the life course. Below is a summary of the 3 themes that most closely correspond with this submission.

Theme 1 – Placing women's voices at the centre of their health and care

- Our submission highlights that too often women's voices are not being listened to within the health and social care system regarding patient safety.
- We note how in design and data a focus on male experience can create serious patient safety issues.

Theme 2 – Improving the quality and accessibility of information and education on women's health

- Our submission emphasises the importance of involving and engaging women effectively in their care and patient safety, providing the access and information they require to enable this.

Theme 5 – Ensuring research, evidence and data support improvements in women's health

- We set out the need for medical studies to be representative of males and females and the importance of disaggregating data by sex so that differences in the effectiveness and risks associated with medical interventions and treatments are available for analysis.

Restorative justice

In addition to the content in our evidence-based blog in the next eight pages of this document, we also believe another issue that should be considered as part of the Women's Health Strategy is more broadly how the healthcare system responds when harm happens to women. This is closely linked with the women expressing concerns that their experiences are too often dismissed and ignored, tying in with *Theme 1 – Placing women's voices at the centre of their health and care* in this Strategy.

We believe one approach to tackling this issue is using restorative justice approaches and practices in response to harm. A restorative approach is intended to create a safe space to explore multiple experiences and perspectives of harm. This allows patients to be heard, listened to, and respected. By patients, clinicians, healthcare leaders and policy makers engaging with one another on patient safety, it can help to establish trust with the patient. This can also provide the impetus for learning and action to be taken to prevent future harm.

We commend the approach adopted by [New Zealand's Ministry of Health in how it responded to harm from surgical mesh](#) and the impact this has had on improvements in patient safety. Closer to home, there are some beacons of good practice within the NHS, such as the [Mersey Care NHS Foundation Trust](#). We believe that the NHS should do more to share and promote a just and learning culture, asking organisations to develop and publish goals on their progress.

Dangerous exclusions: The risk to patient safety of sex and gender bias

A blog by Patient Safety Learning (8 March 2021)

Summary

Today, Patient Safety Learning stands with others around the world to celebrate [International Women's Day 2021](#). In light of this year's campaign theme "choose to challenge" we are raising awareness of some of the ways in which male bias can negatively impact on patient safety.

Drawing on case studies and quantitative research, this blog focuses on three key areas:

1. Design – using examples to illustrate how male-centric design of equipment and medical devices affects patient safety.
2. Data – discussing how data which does not account for differences between the sexes impacts on patient safety.
3. Dismissal – considering the recurring theme from personal testimonials, and healthcare scandals in recent years, that women's voices and patient safety concerns are being ignored or dismissed.

We will reflect on the key patient safety issues and inequalities in each of these areas and offer our perspective on what needs to happen moving forward to prevent future avoidable harm.

Design

PPE

The COVID-19 pandemic has shone a spotlight on male bias in design within healthcare in relation to Personal Protective Equipment (PPE). It became clear that respiratory PPE was leaving female workers at greater risk of exposure to the virus, discomfort, and interference with their ability to work.^[1] This is not a new discovery, with a 2016 survey highlighting that only 3/10 women in the UK had PPE that was designed for the female frame.^[2] This seems particularly inexcusable in the NHS where three quarters of the workforce are female.^[3]

These design issues have serious patient safety implications for infection prevention and control. Female staff are potentially at greater risk of infection, threatening both their personal health and a further depletion of an already stretched workforce, which would inevitably impact on the delivery of safe care. Providing staff with ill-fitting masks also leaves patients vulnerable to the possibility that asymptomatic staff could pass the virus to them, risking an increase in COVID-19 hospital acquired infections.

Surgical equipment

Another area of concern is around the design of surgical instruments, specifically those that have been developed for larger hands and can often be less easy to hold and operate for female staff.^[4] Differences in thumb size or grip strength can make the user-experience extremely variable, with smaller digits left floating in handle holes and many female staff needing to sustain greater levels of force to use the equipment.

Patient Safety Learning believe it is crucial that patient safety is considered as a core part of the design and development of medical equipment and devices. These need to be safe in use and account for the people who will be using them. Although humans are remarkably good at adjusting, patients would clearly benefit from being operated on by surgeons whose tools make it easier, rather than harder, to do their work.

Medical devices

In recent years we have become increasingly aware of the serious patient safety concerns associated with a range of medical devices predominantly used for women, such as pelvic mesh. But there is also evidence that medical devices which are otherwise seen as gender neutral, such as hip implants, can pose greater risks to female patients.^[5]

One hip implant (the DePuy articular surface replacement) has left women around the world with serious complications, including inflammation, painful growths, dislocations, and metal toxicity. These side effects have been associated with a lack of consideration for differences between the sexes in relation to hip movement, with such issues being far less prevalent in male patients.^[6]

What needs to happen?

Patient Safety Learning believes:

- The diversity of user-experience needs to be valued and prioritised at every stage of the design process of medical equipment and devices to ensure that patient safety is not compromised.
- Further research is needed to understand the extent to which sex-biased design exists within healthcare and poses a risk to patient safety.
- Where existing evidence highlights patient safety risks of biased design, clear plans and timelines need to be set out to address unresolved issues. This is an issue that needs to be prioritised by industry and regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA).

Data

Data gathered in medical studies is often not collated in a way whereby differences between the sexes can be analysed and understood.^[7] This may be partly due to the fact that many trials include very low percentages of female cells or subjects (whether human or animal), or none at all,^{[8][9]} making it impossible to draw any sex-specific conclusions.^[10] This tendency to exclude females has even been evident in studies based on conditions that are more common in, or only relevant to, women.^[11] And yet, the results are seen as valid for both sexes.

Tested on males, safe for all?

Research shows sex differences in our organ systems, tissues, and cells.^[12] ^[13] There are differences in the way male and female hearts function,^[14] our lung capacity,^[15] metabolic reactions^[16] and the way our hormones influence medication.^[17] The way men and women are affected by common diseases also varies in severity, prevalence, and nature^[18]; and they can react differently to drugs and treatments. Critically for the safety of such treatments, this could mean an increased or decreased likelihood of survival.

Where drugs have been tested and deemed to be safe, but the data has not been disaggregated by sex and the participants have predominantly or solely been male, we are

unable to truly understand how they affect the female body. Even where females have been excluded from early stages of trials (e.g. with male mice samples) but included at later stages, there is a risk that treatments which may be effective for women have already been ruled out due to their ineffectiveness on the male mice.

As Caroline Criado Perez puts it in *Invisible Women: Exposing Data Bias in a World Designed for Men*:

“The specific effect on women of a huge number of existing medications is simply unknown.”[19]

Life-saving interventions missed: A case study

The importance of sex disaggregated data has been highlighted by the trials of the cardiac resynchronisation therapy device (CRT-D), which is essentially a pacemaker. Based on data taken from studies, the pacemakers were previously deemed to be beneficial for anyone whose heart takes 150 milliseconds or longer to complete a full electrical wave. Guidelines reflected this, meaning anyone with a lower score would not be offered a CRT-D implant. The problem with this approach however was that the trials only included 20% of female participants, but when data from several trials was combined and analysed it became clear that women reacted differently to the device. Female participants with a lower reading of 130-49 milliseconds, who had had the pacemaker fitted, were found to have a 76% reduction in heart failure or death.[20] Had the data been analysed by sex from the start, this evidence could have been used to expand the use of CRT-D implants and improve outcomes for many women.

What needs to happen?

Patient Safety Learning believes that:

- Medical studies should be representative of females, and where they are not included, the rationale should be clearly set out, evidenced and undergo appropriate scrutiny.
- Where males and females are included in medical studies, the data should be disaggregated by sex so that differences in the effectiveness and risks associated with medical interventions and treatments are available for analysis.
- Where female sample sizes are not representative, this should be made clear when reporting the limitations of the study.

Dismissal

Labelled anxious, depressed or irrational

Studies and testimonials indicate that women are more likely to have their physical symptoms attributed to psychological issues by clinicians,[21] [22] [23] [24] with many feeling that clinicians had dismissed them as hysterical.[25] This can manifest itself in various ways:

- One study showed that, of the subjects who had not reported feeling depressed, women were twice as likely as men to be prescribed antidepressants.[26]
- Women who go to A&E are also less likely than men to be given adequate pain relief and more likely to be given anti-anxiety drugs.[27]
- Women with chronic pain are more likely to be wrongly diagnosed with mental health conditions.[28]

These responses can lead to delays in diagnosis and treatment for underlying physical conditions, leaving them at greater risk of poor outcomes or premature death.

Criado Perez tells the story of a young woman who spent a decade seeking help for atypical bowel movements and was told that she needed to be less anxious and less stressed, that it was “all in her head”. When she was eventually referred for a colonoscopy, they found that half of her colon was diseased and that the delay in diagnosis had left her at an increased risk of developing cancer.[29]

This is not an isolated incident. Studies show that women are more likely to experience longer delays in diagnosis for a brain tumour[30], and 6 out of 11 types of cancer.[31] It is widely recognised that delays in cancer diagnoses and treatment increase the risk of mortality.[32]

Unheard and undervalued

Last year, the Cumberlege Review[33] highlighted a number of patient safety failings[34] in relation to pelvic mesh implants, sodium valproate and hormone pregnancy tests. The scale and severity of avoidable harm that resulted from these three interventions over a period of several decades is shocking and could have been reduced if the women involved were listened to sooner and critically, if they had been appropriately informed in the first place. The review found that the women involved had been dismissed and sidelined for years as they fought hard to raise awareness of the issues and prevent others from suffering as they had. The defensive and unresponsive attitudes the women were met with highlighted a shameful disregard for the value of their voices in improving patient safety.

Unfortunately, the reluctance to listen to groups representing patient safety concerns for women is not uncommon. For many years, the Campaign Against Painful Hysteroscopy (CAPH) has been raising awareness of the severe pain experienced by a significant number of women, during outpatient hysteroscopy procedures. Despite the severity and long-lasting nature of the trauma experienced by these women, the systems response has so far been inadequate,[35] and women are continuing to suffer avoidable harm.[36]

What needs to happen?

Patient Safety Learning believes that systems and policies need to be tackled urgently to address the sex and gender bias that results in avoidable harm. We call for the following action.

1. Women, and patient groups representing women:
 - to be given ample opportunity to voice their concerns through feedback, reporting systems and in formal patient reported outcomes analysis
 - to be listened to and believed
 - to be invited to contribute to patient safety as part of the clinical team and in research.
2. Healthcare leaders to commit to using the insights from women, and patient groups representing women, to inform improvement actions that will prevent future harm.
3. Quality, evidence-based gender bias training to be made mandatory for all staff working in healthcare, whether they are clinicians, researchers, product manufacturers, policy makers etc.
4. Data regarding delays in diagnosis and treatment to be disaggregated by sex, regularly reviewed and used to inform further research and to improve outcomes.

Final thoughts and intersectionality

There is still a long road ahead to tackle sex and gender related bias in healthcare, and attitudes towards female patients.

The ancient belief that the male body is the 'norm' runs dangerously deep and has contributed to a widespread acceptance that female-specific data is not necessary or even particularly relevant. This lack of data has left the medical world better equipped to diagnose, treat and care for male patients. In the absence of a comparable level of knowledge and understanding of the female body, women are being too easily labelled or dismissed as anxious without clinical investigation. A convenient labelling system that provides a smokescreen for uncertainty, whether applied consciously or not.

As evidence builds that differences between the sexes play a significant role in the use of medications, devices and treatments, things are beginning to change. Although there are huge historical data gaps to fill, physicians are becoming better informed and able to tailor their approach to the female patient, using up-to-date sex-specific data. Guidelines have also been introduced in other countries to encourage improved representation of females in medical studies, although the UK's main funders still make no requirements for gender in research design and analysis to be considered.[37]

Continuing to accept the male body as an adequate representation of all humans is not just antiquated or scientifically incorrect; it costs lives.

While this blog has focused on the dangers of male-focused approaches to design and data, and biased attitudes towards women, it is essential that we recognise there are complex inter-relationships that compound the issue of biological and physical diversity.

There is evidence that systemic and individual biases in healthcare negatively impact on the safety and care of, but not exclusive to, the following groups:

- transgender patients[38] [39] [40]
- healthcare workers[41] [42] [43] and patients[44] [45] [46] [47] from different ethnic backgrounds. The impact here is not uniform, it is complex and manifests itself in different ways among people from Black, Asian and other ethnic backgrounds.
- patients living with a disability[48] [49] [50] and
- patients from socially deprived backgrounds[51] [52] [53].

Intersectionality is an essential consideration. It is important to consider and analyse all variables in order to effectively identify the barriers, and solutions to safer and more equitable care.

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